

Notice of Allowability

Application No.

09/943,984

Applicant(s)

HUNG ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed June 2, 2000 and interview summary of July 6, 2005.
2. ☒ The allowed claim(s) is/are 76-105, 107-109, 111-149, 152-172, 174-183 and 185-189.
3. ☒ The drawings filed on 31 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 7/6/05.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Deborah Crouch, Ph.D.
Primary Examiner
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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mark Wilson on July 11, 2005.

1. Amend claims 76, 107-109, 111, 112, 117, 122, 152-158, 162, 165, 170, 183, 188 and 189.

76. (Currently Amended) A method for suppressing growth of a tumor comprising a *neu* oncogene cell, comprising contacting the cell in the tumor with an E1A gene product and a chemotherapeutic drug in amounts effective to suppress growth of the tumor, wherein the E1A gene product is introduced into the cell by introduction of a nucleic acid encoding the E1A gene product linked to a promoter and obtaining expression of the E1A gene product.

107. (Currently Amended) The method of claim ~~106~~ 76, wherein the E1A gene product is the E1A 12S or 13S gene product.

108. (Currently Amended) The method of claim ~~106~~ 76, wherein the E1A gene product is either the E1A 12S or 13S gene product.

109. (Currently Amended) The method of claim ~~106~~ 76, wherein the ~~E1A gene~~ nucleic acid encodes both the E1A 12S and 13S gene products.

111. (Currently Amended) The method of claim ~~106~~ 76, wherein the ~~gene-nucleic acid~~ encoding the E1A gene product encodes a mini-E1A gene product.

112. (Currently Amended) The method of claim ~~106~~ 76, wherein the ~~gene-nucleic acid~~ encoding the E1A gene product is introduced into the cell using an E1A nucleic acid/lipid complex.

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117. (Currently Amended) The method of claim ~~106~~ 76, wherein the E1A gene product is introduced into the cell by introduction of a vector containing a gene encoding the E1A gene product.

122. (Currently Amended) A method for suppressing growth of a *neu*-mediated cancer in an animal having or suspected of having the cancer comprising administering to the animal an effective combination of E1A gene product and chemotherapeutic drug in an effective amount to suppress growth of the cancer, wherein the E1A gene product is administered by introducing to the animal a nucleic acid encoding the E1A gene product linked to a promoter and obtaining expression of the E1A gene product.

152. (Currently Amended) The method of claim ~~151~~ 122, wherein the E1A gene product is the E1A 12S or 13S gene product.

153. (Currently Amended) The method of claim ~~151~~ 122, wherein the E1A gene product is either the E1A 12S or 13S gene product.

154. (Currently Amended) The method of claim ~~151~~ 122, wherein the E1A gene encodes both the E1A 12S and 13S gene products.

155. (Currently Amended) The method of claim ~~151~~ 122, wherein the gene encoding the E1A gene product is introduced to the animal by introduction of an adenovirus.

156. (Currently Amended) The method of claim ~~151~~ 122, wherein the gene encoding the E1A gene product encodes a mini-E1A gene product.

157. (Currently Amended) The method of claim ~~151~~ 122, wherein the gene encoding the E1A gene product is introduced to the animal using an E1A nucleic acid/lipid complex.

158. (Currently Amended) The method of claim ~~151~~ 122, wherein the lipid comprises DOTMA, DOPE, or DC-Chol.

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162. (Currently Amended) The method of claim ~~151~~ 122, wherein the E1A gene product is administered by introducing to the animal a vector containing a gene encoding the E1A gene product.

165. (Currently Amended) A pharmaceutical composition comprising nucleic acid encoding an E1A gene product linked to a promoter and a chemotherapeutic drug in a pharmaceutically acceptable carrier.

170. (Currently Amended) The composition of claim 169, wherein the plant alkaloid is vincristine~~[[,]]~~ or vinblastine ~~or paclitaxel~~.

183. (Currently Amended) The composition of claim 182, wherein the antineoplastic agent is ~~selected from the group consisting of cisplatin, VP16, and~~ or TNF.

188. (Currently Amended) A therapeutic kit comprising~~[[,]]~~ a pharmaceutical formulation of a nucleic acid encoding an E1A gene product and a pharmaceutical formulation of a chemotherapeutic drug.

189. (Currently Amended) The kit of claim 188, wherein the pharmaceutical formulation of a nucleic acid encoding an E1A gene product and the pharmaceutical formulation of a chemotherapeutic drug are present within distinct containers.

2. Cancel claims 106, 110, 150, 151, 173 and 184.

Examiner's Comment:

The title has been changed to -Nucleic Acid Encoding an E1A Gene Product Sensitizes Her-2/*Neu* Overexpressing Cancer Cells to Chemotherapy--.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

July 13, 2005